



JAN 25 2011

## 510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: k103271."

Submitter: Maine Standards Company  
Address: 765 Roosevelt Trail  
Windham, ME 04062  
Telephone: 207-892-1300  
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Contact: Holly A. Cressman, Mgr. QA/RA

Summary prepared on: October 29, 2010

Device classification name: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)  
Device description: Quality control material (assayed and unassayed)  
Proprietary Name: MSC Lipid Control  
Regulation Number: 21 CFR 862.1660  
Product Code: JJY  
Regulatory Class: Class I

**Predicate Device:**

Bio-Rad Liquichek™ Lipids Control Level 1 and 2 (K012513).  
MSC Lipid Control (without Apo AI and Apo B) (K082067)

**Device description:**

The MSC Lipid Control is a human serum based liquid quality control containing stabilized HDL-C, LDL-C, CHOL, TRIG, Apo AI, and Apo B of human origin.

Material of human origin used in the manufacture of this MSC Lipid Control kit was tested at the donor level using FDA approved methods.

**Intended use:**

The MSC Lipid Control is intended for use as an assayed quality control material to monitor the ongoing precision of clinical laboratory systems for the following analytes: High-density Lipoprotein Cholesterol (HDL-C), Low-density Lipoprotein Cholesterol (LDL-C), Total Cholesterol (CHOL), Triglycerides (TRIG), Apolipoprotein AI (Apo AI), and Apolipoprotein B (Apo B), on the instruments listed in the value sheet.

**Summary:**

The information provided in this pre-market notification demonstrates that the performance of MSC Lipid Control is substantially equivalent in form and function to the predicate devices for its stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Maine Standards Company  
c/o Holly Cressman, Manager, QA/RA  
765 Roosevelt Trail  
Windham, ME 04062

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: k103271/S001

JAN 25 2011

Trade Name: MSC Lipid Control  
Regulation Number: 21 CFR §862.1660  
Regulation Name: Quality Control Material (assayed and unassayed)  
Regulatory Class: Class I, reserved  
Product Codes: JJY  
Dated: December 21, 2010  
Received: December 29, 2010

Dear Ms. Cressman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

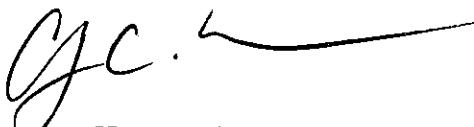
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Courtney Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## **Indications for Use**

510(k) Number: k103271

Device Name: MSC Lipid Control

### Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
510(k) k103271

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